

§ 807.26

of devices previously submitted on form FDA-2892.

(2) The Code of Federal Regulations citation for any applicable standard for the device under section 514 of the act or section 358 of the Public Health Service Act.

(3) The assigned Food and Drug Administration number of the approved application for each device listed that is subject to section 505 or 515 of the act.

(4) The name, registration number, and establishment type of every domestic or foreign device establishment under joint ownership and control of the owner or operator at which the device is manufactured, repackaged, or relabeled.

(5) Whether the device, as labeled, is intended for distribution to and use by the general public.

(6) Other general information requested on form FDA-2892, i.e.,

(i) If the submission refers to a previously listed device, as in the case of an update, the document number from the initial listing document for the device,

(ii) The reason for submission,

(iii) The date on which the reason for submission occurred,

(iv) The date that the form FDA-2892 was completed,

(v) The owner's or operator's name and identification number.

(7) Labeling or other descriptive information (e.g., specification sheets or catalogs) adequate to describe the intended use of a device when the owner or operator is unable to find an appropriate FDA classification name for the device.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37998, Aug. 25, 1978; 58 FR 46523, Sept. 1, 1993; 64 FR 404, Jan. 5, 1999; 66 FR 59160, Nov. 27, 2001; 69 FR 11312, Mar. 10, 2004]

§ 807.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, or location of an operation defined in § 807.3(c) shall be submitted on Form FDA-2891(a) at the time of annual registration, or by letter if the changes occur at other times. This information shall be submitted within 30 days of such changes. Changes in the names of

21 CFR Ch. I (4-1-12 Edition)

officers and/or directors of the corporation(s) shall be filed with the establishment's official correspondent and shall be provided to the Food and Drug Administration upon receipt of a written request for this information.

[69 FR 11312, Mar. 10, 2004]

§ 807.30 Updating device listing information.

(a) Form FDA-2892 shall be used to update device listing information. The preprinted original document number of each form FDA-2892 on which the device was initially listed shall appear on the form subsequently used to update the listing information for the device and on any correspondence related to the device.

(b) An owner or operator shall update the device listing information during each June and December or, at its discretion, at the time the change occurs. Conditions that require updating and information to be submitted for each of these updates are as follows:

(1) If an owner or operator introduces into commercial distribution a device identified with a classification name not currently listed by the owner or operator, then the owner or operator must submit form FDA-2892 containing all the information required by § 807.25(f).

(2) If an owner or operator discontinues commercial distribution of all devices in the same device class, i.e., with the same classification name, the owner or operator must submit form FDA-2892 containing the original document number of the form FDA-2892 on which the device class was initially listed, the reason for submission, the date of discontinuance, the owner or operator's name and identification number, the classification name and number, the proprietary name, and the common or usual name of the discontinued device.

(3) If commercial distribution of a discontinued device identified on a form FDA-2892 filed under paragraph (b)(2) of this section is resumed, the owner or operator must submit on form FDA-2892 a notice of resumption containing: the original document number of the form initially used to list that device class, the reason for submission,